REMARKS

The Office Action has rejected Claims 1, 2, 35, 68 and 88 under 35 U.S.C. §103 as defining subject matter which is allegedly rendered obvious by the teachings in U.S. Patent No. 3,995,059 to Fukumaru et al. ("Fukumaru et al."). Further, Claims 10, 85 and 86 are rejected under 35 U.S.C. §112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Further, Claims 1 and 2 are rejected under 35 U.S.C. §102(b) as defining subject matter which is allegedly anticipated by the teachings in JP 101-201352 ("JP '352"). (It is noted that the Office Action has transposed from the "2" and the "5" in citing this art. Applicants have assumed that the citation should be JP 101-201352. Correction of the record is respectfully requested.) Further, Claims 1, 2, 35, 36 and 68 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by the teachings of GB-1,110,612 ("GB '612"). In addition, Claims 74 and 75 are rejected under 35 U.S.C. § 102(b) as defining subject matter which is allegedly anticipated by the teachings of U.S. Patent No. 4,877,789 to Shroot et al. ("Shroot et al."). Finally the Office Action has objected to Claims 3-9 and 76-87, but has indicated that the subject matter therein is allowable if rewritten in independent form.

The Applicants have amended the claims which when considered with the comments hereinbelow, are deemed to place the present application in consideration for allowance. Favorable action is respectfully requested.

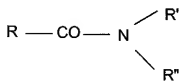
Applicants have amended Claims 1, 35 and 85 by amending the definition of R_5 and R_6. R_5 has been amended to recite that it can be a lower alkyl, aryl, aryl lower alkyl or fatty group containing 11-29 carbon atom or R_7, that is, the scope as originally defined. R_6 is defined to be R_7. Support is found in Paragraphs 9-15 in Page 3 of the instant specification. As originally

defined, R_5 and R_6 were independently lower alkyl, aryl, aryl lower alkyl or fatty group containing 11-29 carbon atoms or R_7. In other words as originally defined, R_5 and R_6 may be the same or different. As defined in the present claims, R_5 is as originally defined and R_6 is R_7. However, as indicated hereinabove, R_5 and R_6 are independently defined, meaning that when R_6 is R_7 and R_5 is R_7, then R_5 may have a different meaning of R_7 than R_6. Thus, Applicants have utilized the term "independently" in defining R_6 in Claims 1, 35 and 85 to denote that when R_5 is R_7, then R_6 may be the same or different. Applicants have amended Claim 10 by inserting the structure for the two compounds recited therein. Claim 85 has been similarly amended. These compounds were prepared, as described in Examples 25 and 27, respectively, of the instant specification. The structure of those products have the structure indicated in the Claims.

No new matter is added to the application.

Pursuant to the rejection of Claims 1, 2, 35, 68 and 88 the Office Aciton cites Fukumaru et al. and specifically Columns 159, 161 and 169 thereof.

Fukumaru et al. disclose compounds of the formula



and pharmaceutical compositions containing same, wherein R is a C_{13} - C_{25} aliphatic hydrocarbon chain or a C_{13} - C_{25} hydrooxylated aliphatic hydrocarbon chain and RCO- is other than isostearoly; R' is d- or *l*-α-C_1 – C_4 alkylbenzyl, racemic-, d- or *l*-α-C_1 – C_4 alkylbenzyl substituted in the benzene ring with one or two substituents selected from the group consisting of C_1 – C_4 alkyl, C_1 – C_4 alkoxy, halogen and nitro, or racemic-, d- or *l*-α-benzylbenzyl; R" is hydrogen; or R' and R" together are cyclohexyl; and when RCO- is isotearoyl, R' is alkyl,

alkenyl, cycloalkyl, alkylcycloalkyl, hydroxycycloalkyl, alkoxycycloalkyl, alkylphenyl, hydroxyphenyl, alkoxyphenyl, halogenophenyl, halogen-alkyl-substituted phenyl, halogenoalkyl-and halogen-substituted phenyl, alkoxy-and halogen-substituted phenyl, benzyl, racemic-, d-, or *l*-α-$C_1 - C_4$ alkylbenzyl, benzyl substiturted in the benzene ring with lower alkyl or lower alkoy, racemic-, d-, or *l*-α- benzylbenzyl or hydroxybenzyl, and R" is hydrogen or any one of the groups represented by R', and a pharmaceutically acceptable carrier. It alleges that these compounds are useful for lowering elevated cholesterol in the blood.

It is to be noted that as defined in Fukumaru et al., neither R' nor R" can have both an oxyphenyl substituent and a second ether functionality on the same side chain attached to the phenyl ring, i.e., O-R_2-O-R_3- attached to the phenyl ring. In other words none of the substituents of R' or R" in Fukumaru et al. can have R_7, i.e., R_1-Ar-O-R_2-O-R_3- attached to the amide nitrogen. A review of the structures in Fukumaru et al. in Columns 159, 161 and 169 clearly reveals that any amide formed will not have any such substituent as R_7 substituted on the amide nitrogen. On the other hand, as defined, at least one of the substituents on the amide nitrogen is R_7.

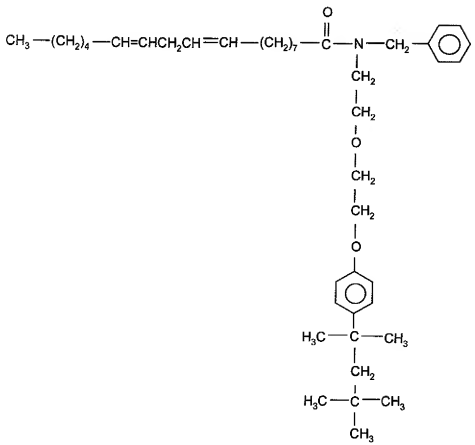
Case law has held that anticipation requires that the prior art reference describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation. Atlas Power Co. v. Ireco, Inc., 190 F.31 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999) The exclusion of a claimed element from a prior art reference is enough to negate anticipation by the reference. Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771-772, 218 USPQ781, 789 (Fed. Cir. 1983).

Thus, inasmuch as none of the structures in Fukumaru et al. can have R_7 on the amide nitrogen and inasmuch as the compounds recited in the rejected claims have the R_7 substituted on

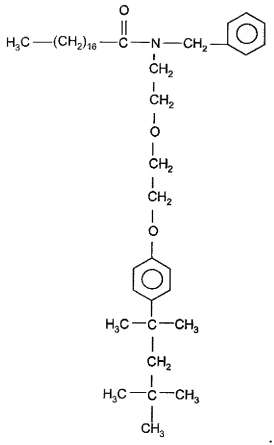
the amide nitrogen, Fukumaru et al. do not anticipate the subject matter of Claims 1, 2, 35, 68 and 88. Thus, this rejection under 35 U.S.C. § 102(b) is obviated; withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims, 10, 85 and 86 under 35 U.S.C. §112, second paragraph, the Office Action alleges that the subject matter therein is not within the scope of Claim 76. However, contrary to the allegations in the Office Action, these compounds are within the scope of the claims.

The structure of benzethonium linoleamide is:



while that of benezethonium stearamide is



Thus, there is antecedent basis for these structures in the recited subject matter recited in Claims 10, 85 and 86. More specifically, R_5 is benzyl, R_6 is R_7 and R_4 is a fatty group. Therefore, the rejection of Claims 10, 85 and 86 under 35 U.S.C. §112, second paragraph is obviated. Withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 1 and 2 under 35 U.S.C. §102(b), the Office Action cites JP' 352.

JP '352 does not teach, disclose any tertiary amide containing R_7 as one of the substituents on the amide nitrogen.

Applicants are enclosing a translation of JP '352. It is respectfully requested that this translation be made of record.

As defined, the substituents on the amide nitrogen in JP '352 are A and R'. R' is an alkyl group or alkenyl group of 8-22 carbons and A is an alkyl group or alkenyl group of 8-22 carbons or a hydrogen atom. None of these amides shown in JP '352 have the substituent R_7, i.e., R_1-Ar-O-R_2-O-R_3-, on the amide nitrogen.

Inasmuch as the subject matter of Claims 1 and 2 require that one of the substituents on the amide nitrogen be R_7 and inasmuch as none of the compounds disclosed or described in JP '352 have this R_7 substituent on the amide nitrogen, the compounds in JP '352 do not teach or disclose the subject matter recited in Claims 1 or 2. Thus, JP '352 does not anticipate the subject matter of Claims 1 and 2. Consequently, this rejection under 35 U.S.C. §102(b) is obviated, withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 1-2, 35-36 and 68 under 35 U.S.C. §102(b), the Office Action cites GB '612.

GB '612 does not teach or disclose an amide wherein one of the substituent is R_7. A review of the structures on Pages 4, 6 and 8 of GB '612 reveals that in GB '612, at least one of the substituents on the amide nitrogen atom is either a hydrogen atom or a lower alkyl group or phenyl group or substituted phenyl group, phenylalkyl, or cycloalkyl group or substituted cycloalkyl or the two substituents on the nitrogen atom together form a ring, such as pyrrolyl. Moreover, on Page 8 thereof, GB '612 lists o-methoxyphenyl as one of the substituents on the amide nitrogen atom. However, there is no substituent listed that has R_7, i.e., R_1-Ar-O-R_2-O-R_3-substituent, on the amide nitrogen, as claimed in the rejected claims.

Thus, since the R_7 substituent on the amide nitrogen is not disclosed or taught in any of the structures described in GB '612 and since the subject matter in the rejected claims require that R_7 be present on the amide nitrogen, the subject matter of the rejected claims is not anticipated

by the teachings of GB '612. Thus, this rejection is obviated; withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 74 and 75 the Office Action cites Shroot et al. The Office Action has rejected these claims, alleging that Shroot et al. disclose tertiary amide hydrates. More specifically, the Office Action refers to the teachings in Columns 1-2 and 7-8, to support its rejection.

Shroot et al. do not teach or disclose any amide hydrates - - let alone tertiary amide hydrates. A review of Shroot et al. clearly shows that there is no specific reference to hydrates therein. However, the Office Action alleges that the salts of inorganic acid encompasses hydrates.

Applicants disagree. Shroot et al. refer to salts of inorganic and organic acids such as hydrochloric, lactic, tartaric and citric acids. A hydrate is neither an inorganic nor organic acid. By definition, a hydrate is not a salt; it refers to a water molecule being associated with a compound. Applicants are enclosing herewith a definition of hydrate from a chemical dictionary. It is clear from the definition that a hydrate requires the presence of water associated with the compound. Thus, it is respectfully submitted that any allegation in the Office Action regarding a teaching of a salt disclosing a hydrate is misplaced and is not correct. Thus, there is no specific teaching therein of any hydrate in Shroot et al.

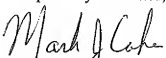
Since Shoot et al. do not disclose hydrates and since the subject matter of Claims 75 and 76 is directed to hydrates, this rejection is obviated; withdrawal thereof is respectfully submitted.

The Office Action has objected to Claims 3-9 and 76-87, for being dependent upon a rejected base claim. However, in view of the above, the rejections of the base claims upon which

these aforementioned claims are dependent are overcome. Withdrawal of the objections to Claims 3-9 and 76-87 is respectfully requested.

Thus, in view of the Amendment to the Claims and the Remarks hereinabove, it is respectfully submitted that the present case is in condition for allowance, which action is earnestly solicited.

Respectfully Submitted,



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Encls. PTO 1449
Definition of hydrate